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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/089,835 | 10/28/2002 | Kouichi Ishikawa | 112387 | 5261 |

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Oliff & Berridge
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Alexandria, VA 22320

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| EXAMINER |
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MALLARI, PATRICIA C

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| ART UNIT | PAPER NUMBER |
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3735

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 12/21/2006 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/089,835

Applicant(s)

ISHIKAWA ET AL.

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 21-32 is/are rejected.
- 7) ☒ Claim(s) 33 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This is a non-final Office action. New grounds of rejection are presented which were not necessitated by the applicants' amendment to the claims. The allowability of claims 1 and 2 is regretfully withdrawn in light of the rejections set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites, "A method of testing for hepatic diseases comprising collecting breath, quantifying isopropanol and/or cyanides in the breath, and analyzing a result thereof." The method, as claimed fails to provide a physical transformation or reduction of an article to a different state or thing and further fails to set forth a practical application that produces a useful, concrete, and tangible result. The culmination of the claimed method is "analyzing a result", which analysis appears to be a mere abstraction. In order to be considered statutory subject matter, the method must have a practical application producing a useful, concrete, and tangible result. See MPEP § 2106.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 10, 11, 21-23, 28, 29, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,221,026 to Phillips. Phillips discloses an breath analyzing apparatus and method wherein a breath collecting section is provided for introducing and collecting breath to be analyzed, a breath analyzing section quantifies isopropanol in the breath, and a data processing section analyzes the quantified result obtained by the breath analyzing section (see entire document, particularly col.10, lines 42-61; col. 13, lines 27-43; col. 14, lines 47-50; col. 20, line 22 of Phillips). The analysis of Phillips is for detection or testing for breast cancer, ischemic heart disease, and heart transplant rejection (see entire document, particularly col. 15, line 7-col. 17, line 45 of Phillips), rather than for hepatic disease. However, the examiner takes official notice that it is well known in the art for a doctor or other clinical staff to test for multiple related diseases, particularly upon suspicion of a single disease, in order to provide the most accurate diagnosis and effective treatment for the patient. Additionally, breast cancer commonly spreads to the liver, thereby resulting in liver cancer, which is a hepatic disease, and the risk of heart disease and hepatic cirrhosis are casually related. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method and apparatus of Phillips to test for liver disease, since Phillips teaches testing for breast cancer or ischemic heart disease, and it is known that breast cancer ischemic heart disease and liver disease are related and that one of

ordinary skill in the art would test for related diseases in order to provide accurate diagnosis and effective treatment of the patient.

Regarding claims 4, 5, 11, 22, 23, and 29, the breath collecting section consists of a breath collecting means and a breath transfer means (see entire document, particularly col. 10, lines 41-59 of Phillips). With further regard to claims 11, 29, and 31, the breath analyzing section comprises a mass spectrometer (see entire document, especially col. 10, lines 66-67 of Phillips).

Regarding claims 10 and 28, the breath analyzing section comprises a mass spectrometer (see entire document, especially col. 10, lines 66-67 of Phillips).

Claims 6-9, 12, 13, 24-27, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips, as applied to claims 1, 3-5, 10, 11, 21-23, 28, 29, and 32, and further in view of US Patent No. 5,573,005 to Ueda. Phillips describes a system having a heated, portable, microprocessor-controlled breath collection apparatus and gas chromatograph, but fails to describe the system, particularly the breath collection apparatus in detail. However, Ueda discloses a heated, portable, microprocessor-controlled breath collection apparatus and gas chromatograph for collecting and analyzing expiration from a user (see entire document, especially fig. 1; col. 2, line 46- col. 3, line 65; col. 4, lines 11-26 of Ueda). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the system of Ueda as that of Phillips since Phillips teaches using a system comprising a breath collection apparatus and gas chromatograph, and Ueda describes such a system.

Regarding claims 6 and 24, the breath collecting means is a communicating opening for connecting a breath container 12 (see entire document, especially fig. 1; col. 5, lines 1-35 of Ueda).

Regarding claims 7-9, 12, 13, 25-27, 30, and 31 the breath transfer means comprises a duct that connects the breath collecting means 4, 6, 8, with the breath analyzing section 14 (see entire document, especially fig. 1; col. 5, lines 24-30 of Ueda). With further regard to claims 8 and 26, the breath transfer means further includes a pump means (piston of syringe 12 and motor 12) to send breath to the breath analyzing section (see entire document, especially col. 5, lines 17-30 of Ueda). With further regard to claims 9, 13, and 27, the breath collecting means includes a mouthpiece 8 (see entire document, especially col. 5, lines 1-2 of Ueda), a communicating opening for connecting a breath container 12 (see entire document, especially fig. 1 of Ueda), and valve means 10 which can be switched so that only one of the mouthpiece 8 and the breath container 12 communicates with the breath analyzing section 14 (see entire document, especially col. 15, lines 17-30 of Ueda). With further regard to claims 12, 13, and 30, the breath analyzing section comprises a mass spectrometer (see entire document, especially col. 10, lines 65-67 of Phillips).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 33 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The allowability of claims 33 and 34 was addressed in the Office action filed 11/17/04 and is repeated below.


The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 33 and 34, the prior art of record fails to teach or fairly suggest a breath analyzing apparatus wherein at least cyanides in the breath are quantified, in combination with all of the other limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735



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37 CFR 1.105 REQUIREMENT FOR INFORMATION

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.
2. The application file suggests that the applicant likely has access to information necessary to a more complete understanding of the invention and its context. In accordance with 37 CFR 1.105 and MPEP 704.11(a), subsections A, C, F, O, and P, the applicant (or the assignee) is respectfully requested to disclose the following:
 - a. In response to this requirement, please provide a copy and English translation, if necessary, of each of the following items of art referred to on lines 1-4 of p.2 of the applicants' specification: Yasuhiro Mitsui, "detection system of trace components in breath", bulletin of S14-5 Showa 62 National Convention of Institute of Electrical Engineers of Japan (1987)
 - b. In response to this requirement, please provide copies of each publication which any of the applicants authored or co-authored and which describe the disclosed subject matter of testing for hepatic disease using breath components and/or testing for hepatic disease by quantifying isopropanol and/or cyanide.

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- c. In response to this requirement, please provide the title, citation and copy of each publication that is a source used for the description of the prior art in the disclosure. For each publication, please provide a concise explanation of that publication's contribution to the description of the prior art.
- d. In response to this requirement, please provide the title, citation and copy of each publication that any of the applicants relied upon to develop the disclosed subject matter that describes the applicant's invention, particularly as to developing a method and apparatus for detecting hepatic disease based on a quantification of isopropanol and/or cyanide. For each publication, please provide a concise explanation of the reliance placed on that publication in the development of the disclosed subject matter.
- e. In response to this requirement, please provide the title, citation and copy of each publication that any of the applicants relied upon to draft the claimed subject matter. For each publication, please provide a concise explanation of the reliance placed on that publication in distinguishing the claimed subject matter from the prior art.
- f. In response to this requirement, please state whether any search of prior art was performed. If a search was performed, please state the citation for each prior art collection searched. If any art retrieved from the search was considered material to demonstrating the knowledge of a person having

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ordinary skill in the art to the disclosed method or apparatus for detecting hepatic disease, please provide the citation for each piece of art considered and a copy of the art.

3. This requirement is reasonably necessary to examination because, based on a review of the application file and the prior art, the record suggests that the details of information available to the applicant may be relevant to the issue of patentability and thus shows the need for information in addition to that already submitted by the applicant.
4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.
5. The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the

scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

6. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.
7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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